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EXAMINER

BHAT, NARAYAN KAMESHWAR

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,928	<b>Applicant(s)</b> SQUIRRELL ET AL.	
	<b>Examiner</b> NARAYAN K. BHAT	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 25-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/29/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

1. This office action is written in reply to applicant's correspondence filed November 04, 2008. Claims 1 and 3-16 were amended. New claims 25-47 were added. Applicant's arguments have been thoroughly reviewed and addressed following the rejections.

Applicant's amendment requiring first and second chambers on a platform and first functional component acting as collector for moving the sample from one chamber to the other and a disposable platform necessitate the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

### ***Note***

#### ***35 U.S.C. 112, Sixth Paragraph***

2. The claims as amended do not require analysis under 35 USC 112 sixth paragraph.

### ***Amendments to Claims***

3. Amendments to the claims 1 and 3-16 have been reviewed and entered.

### ***New Claims***

4. New claims 25-47 have been reviewed and entered.

### ***Claim Status***

5. Claims 1-47 are pending in this application. Claims 18-24 are withdrawn.
6. Claims 1-17 and 25-47 are under examination.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 11-12, 15, 17 and 25-33 and 35-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (WO 01/11374 published Feb. 15, 2001, cited in IDS filed October 29, 2008).

*Note:* Claims have been interpreted based on structural components in the claim (MPEP 2114).

Claim 1 recites following structural components: (i) a moveable platform comprising first and second chambers and a first functional component and (ii) an arm for raising and lowering the functional component. Clark et al teaches structural components (i) and (ii) as discussed below

Regarding structural component (i), Clark et al teaches an apparatus comprising a movable reagent carousel, i.e., a moveable platform (Fig. 1, # 4, pg. 8, lines 27- 28 and pg. 34, line 12).

Regarding structural component 'a' Clark et al teaches that reagent carousel comprises a sample receiving element further comprising a reagent channel, i.e., a first chamber suitable for receiving a sample (Fig. 1, # 6, pg. 7, lines 27-29, pg. 34, line 12 and pg. 36, lines 25-29).

Regarding structural component 'b' Clark et al teaches an optical reading well,

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i.e., a second chamber into which an analyte extracted from the sample or a reagents may be delivered (Fig. 1, # 20, pg. 8, lines 29-30 and pg. 34, line 11).

Regarding structural component 'c' Clark et al teaches a reagent well piston, i.e., a first functional component (Fig. 2A, # 24, pg. 8, lines 31-32), which is releasably held in place on the reagent carousel and able to move the reagent from reagent well to the optical reading well (pg. 37, lines 16-33), thus teaching a first functional component as claimed.

Regarding structural component (ii), Clark et al teaches a push rod (i.e., an arm) capable of being raised and lowered and removeably attached to the piston (i.e., a first functional component, Fig. 5B, piston # 24, push rod # 46, pg. 37, lines 16-25) and further teaches a vertical drive element to raise and lower the push rod, i.e., arm (Fig. 5B, # Vertical drive element 44, pg. 37, lines 16-33). Clark et al also teaches that the reagent carousel is moveable and further teaches a rotation motor (Fig. 11, # 114, pg. 42, lines 1-10) such that any chamber or piston (i.e., functional component) may be aligned with respect to the push rod, i.e., an arm.

Regarding claim 2, Clark teaches that the reagent carousel, i.e., platform is circular (Fig. 1, # 4).

Regarding claim 3, Clark et al teaches that the push rod, i.e., an arm that mechanically removeably attaches to the piston hex box (Figs. 5B and 5C, push rod # 40, piston # 24, hex box # 40, pg. 37, lines 16-33).

Regarding claim 4, Clark et al teaches a push rod, i.e., an arm and vertical drive element (Figs. 5B and 5C, # 44) for raising and lowering the arm in a substantial vertical

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direction (pg. 37, lines 16-33).

Regarding claim 5, Clark et al teaches that the apparatus comprises a piston to remove an analyte from the sample (Fig. 53, # 122 and pg. 38, lines 1- 6 and 14-15).

Regarding claim 6, Clark et al teaches that the test surface in the optical reading well, i.e., second chamber comprises film forming particles capable of forming a complex with the analyte (Fig. 1, well # 20, pg. 13, lines 25-27, pg. 14, line 10), which is reasonably interpreted as solid phase binding material.

Regarding claims 11-12, Clark et al teaches that the apparatus comprises a heating unit, i.e., a thermal unit, which is capable of heating the contents of the chamber of the apparatus (pg. 42, lines 27-31).

Regarding claim 15, Clark et al teaches that the reagent well comprises pre-dispensed reagents (Fig. 1, reagent well, # 8, pg. 35, lines 26-27).

Regarding claim 17, Clark et al teaches a sample port for processing of sample (Fig.1, # 6 and pg. 11, lines 6-8) comprising nucleic acids (pg.48, line 25).

Claim 25 recites following structural components: (i) a moveable platform, (ii) a chamber, (iii) a first functional component, (iv) a sealed chamber and (v) an arm. Clark et al teaches structural components (i) to (v) as discussed below

Regarding structural component (i), Clark et al teaches an apparatus comprising a movable reagent carousel, i.e., a moveable platform (Fig. 1, # 4, pg. 8, lines 27- 28 and pg. 34, line 12).

Regarding structural component 'ii' Clark et al teaches a sample receiving element comprising a reagent channel, i.e., a chamber suitable for receiving a sample,

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wherein the chamber is integrated into the platform (Fig. 1, # 6, pg. 7, lines 27-29, pg. 34, line 12 and pg. 36, lines 25-29).

Regarding structural component 'iii' Clark et al teaches a reagent well piston, i.e., a functional component capable of moving a reagent or piercing seals of chambers (Fig. 2A, piston # 24, pg. 8, lines 31-32, reagent well # 8, Fig. 5B, seal # 26, and pg. 37, lines 16-33). Clark et al also teaches that the piston reversibly attaches to a push rod, i.e., an arm of the apparatus (Fig. 5B, push rod # 40, pg. 37, lines 16-33).

Regarding structural component (iv), Clark et al teaches a sample chamber further comprising a membrane to retain reagents for processing of sample (Fig. 53, sample chamber # 6 and pg. 38, lines 1- 12), thus teaching a sealed chamber. Clark also teaches reagents are for removing analytes and analyte comprises nucleic acids (pg.48, line 25).

Regarding structural component (v), Clark et al teaches a push rod (i.e., an arm) capable of being raised and lowered and removeably attached to the piston (i.e., a functional component, Fig. 5B, piston # 24, push rod # 46, pg. 37, lines 16-25) and further teaches a vertical drive element to raise and lower the push rod, i.e., arm (Fig. 5B, # Vertical drive element 44, pg. 37, lines 16-33).

Regarding claim 26, Clark teaches that the reagent carousel, i.e., platform is circular (Fig. 1, # 4)

Regarding claim 27, Clark et al teaches that the apparatus comprises reagent well, i.e., a chamber containing pre-dispensed reagents and is exchangeable (Fig. 2A, # 8, pg. 7, lines 25-34, pg. 35, lines 26-28).

Regarding claims 28-29, Clark et al teaches a barcode for identifying element of the cartridge, which includes chambers in the cartridge and a barcode reader configured to read the barcode (pg. 21, lines 12-15).

Regarding claim 30, Clark et al teaches that the push rod, i.e., an arm that mechanically removeably attaches to the piston hex box (Figs. 5B and 5C, push rod # 40, piston # 24, hex box # 40, pg. 37, lines 16-33).

Regarding claim 31, Clark et al teaches that the piston, i.e., functional component is capable of moving the reagent (Fig. 5B, reagent well #8, piston # 24, pg. 37, and lines 16-33).

Regarding claims 32 -33, Clark et al teaches a heating unit, i.e., a thermal unit, which is capable of heating the contents of the chamber of the apparatus (pg. 42, lines 27-31).

Regarding claim 35, Clark et al teaches a sample processing device for processing of sample (Fig.1, # 6 and pg. 11, lines 6-8) comprising nucleic acids (pg.48, line 25).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising reagents and (iii) a hole for accommodating a functional component. Clark et al teaches structural components (i) to (iii) as discussed below.

Regarding structural component (i), Clark et al teaches a reagent carousel, a platform (Fig. 1, # 4, pg. 35, line 9) comprising a sample receiving element comprising a channel, i.e., a chamber suitable for receiving a sample (Fig. 1, # 6, pg. 7, lines 27-29,



pg. 34, line 12 and pg. 36, lines 25-29).

Regarding structural component (ii), Clark et al teaches a reagent well containing pre-dispensed reagents for use in the processing (Figs. 2A, # 8, pg. 35, lines 26-28) and further teaches chambers are sealed with a sealing label comprising piston I (Fig. 5A, piston # 24, sealing label # 22, pg. 37, lines 16-23).

Regarding structural component (iii), Clark et al teaches that the reagent well has hole for accommodating a piston, i.e., a functional component (Fig. 2A, reagent well # 8, piston # 24, pg. 35, and lines 9-12).

Regarding claim 37, Clark teaches that the reagent carousel, i.e., platform is circular (Fig. 1, # 4).

Regarding claim 38, Clark et al teaches that the apparatus comprises reagent well, i.e., a chamber containing pre-dispensed reagents and is exchangeable (Fig. 2A, # 8, pg. 7, lines 25-34, pg. 35, lines 26-28).

Regarding claim 39, Clark et al teaches a barcode for identifying element of the cartridge, which includes chambers in the cartridge (pg. 21, lines 12-15).

Claim 40 recites following structural components a platform comprising: (a) a chamber, (b) one or more additional chambers and (c) a first functional component. Clark et al teaches structural components (a) to (c) as discussed below.

It is noted that the platform is defined as “disposable”. However none of the structural components of the claimed platform are defined by any special structure that define a disposable property or composition.

Regarding structural component (a), Clark et al teaches a single use disposable

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cartridge comprising a reagent carousel, i.e., a platform (Fig. 3, # 4 and pg. 7, lines 14-33, pg. 35, line 9) comprising a sample receiving element, i.e., a chamber suitable for receiving a sample (Fig. 1, # 6, pg. 7, lines 27-29, pg. 34, line 12 and pg. 36, lines 25-29).

Regarding structural component (b), Clark et al teaches a reagent well containing pre-dispensed reagents for the processing operation (Figs. 3, # 8 and pg. 35, lines 26-28).

Regarding structural component (c), Clark et al teaches a seal, i.e., a first functional component (Fig. 3, # 34, pg. 36, lines 26-28), which is configured to act as collector for moving the sample, an analyte contained therein (Fig. 3 and pg. 36, lines 25-32).

Regarding claim 41, Clark et al teaches that the reagent carousel, i.e., a platform is adapted to carryout sample processing and analysis (pg. 7, lines 27-32).

Regarding claims 42 and 43, Clark et al teaches reagent wells comprising pre-dispensed reagents are sealed with membrane (Fig. 4, Well # 8, Sealing membrane # 22 and pg. 35, lines 25-28, pg. 37, lines 5-15).

Regarding claims 44 and 45, Clark et al teaches a flat piston comprising a breaking tool, i.e., a cutter capable of breaking a seal between the reagent channel and sample well (Fig. 3, reagent channel # 38, differential seal # 34, pg. 36, and lines 25-33). The protruding portion of the piston that cuts the seal, is reasonably interpreted as second functional component of the said claims as defined in the instant specification (instant specification, USPGPUB, paragraph 0014, lines 16-20).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 5-11, 13, 15-16, 25, 32, 34, 40, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (WO 01/11374 published Feb. 15, 2001) in view of Smith et al (USPN 6,027,945 issued Feb. 22, 2000).

Claim 7 is dependent from claim 6, which is dependent from claim 5. Claims 9 and 10 are dependent from claim 6. Claim 13 is dependent from claim 11. Claim 16 is dependent from claim 15. Claims 5, 11 and 15 are dependent from claim 1. Claim 34 is dependent from claim 32, which is dependent from claim 25. Claims 46 and 47 are dependent from claim 40. Teachings of Clark et al regarding claims 1, 5-6, 11, 15, 25 and 40 are described in this office action in section 8.

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Regarding claim 7, Clark et al are silent about solid phase binding material is silica.

Regarding claims 8-10, Clark et al are silent about a magnet and a sheath providing an interface between the separating material and the solid phase material.

Regarding claims 13 and 34, Clark et al are silent about physical processor is capable of sonicating the contents of the chamber.

Regarding claim 16, Clark et al teaches that the reagent well, i.e., a chamber comprises pre-dispensed reagent (pg. 35, lines 26-27) but are silent about reagents bound to a solid phase binding material.

Regarding claim 46, Clark et al teaches a membrane, i.e., a first functional component for separating particulate from the solution (Fig. 53, membrane # 36 and, pg. 38, lines 1-15). Clark et al are silent about a sheath providing an interface between the separating material and the solid phase material.

Regarding claim 47, Clark et al teaches that the reagent well, i.e., a chamber comprises pre-dispensed reagent (pg. 35, lines 26-27) but are silent about processing reagents bound to a solid phase binding material.

As described above, Clark et al are silent about solid phase binding material capable of forming complex with the analyte. However, solid phase binding material capable of forming complex with the analyte was known in the art at the time of the claimed invention was made as taught by Smith et al.

Smith et al teaches solid phase binding material capable of forming complex with the DNA analyte is silica magnetic material (Abstract and column 6, lines 19-20,

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limitations of claims 6-7, 16 and 47) and further teaches that means of attracting DNA analyte -silica magnetic particle complex is a magnet (Abstract and column 12, lines 40-50, limitations of claims 8-9). Smith et al also teaches that the magnetic particles comprising silica provides sheath between the silica attracting material and the DNA complex (Abstract and column 8, lines 46-60, column 9, lines 60-67, column 10, lines 1-5) and the magnet is adjacent to the container, thus teaching that the tissue is the sheath, which provides an interface between the magnet (i.e., the means for attracting the complex) and the DNA-silica-magnetic particle complex (column 12, lines 40-50, limitation of claims 10 and 46).

Regarding claims 13 and 34, Smith et al teaches a sonicator, capable of sonicating the contents of the chamber (column 10, line 45).

Smith et al also teaches that silica magnetic particle provides convenient and efficient means for isolating biological target material of interest and sufficiently free of contaminating material, which can interfere with further analyses and is amenable to being automated (Abstract and column 7, lines 3-30).

Clark et al is interested in processing multiple sample types (pg. 7, lines 25-33) and Smith et al providing solid phase material to isolate nucleic acids free of contamination will improve the quality of the analyte and therefore easily combinable with the apparatus of Clark et al.

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the solid phase material of Clark et al with magnetic solid phase binding material of Smith et al with a reasonable expectation of

success.

An artisan would have been motivated to modify the solid phase material of Clark et al with the expected benefit of having silica magnetic particle providing convenient and efficient means for isolating biological target material of interest and having an analyte sufficiently free of contaminating material, which can interfere with further analyses and is amenable to being automated as taught by Smith et al (Abstract and column 7, lines 3-30).

12. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (WO 01/11374 published Feb. 15, 2001) in view of Lee (WO 98/24548 published Jun. 11, 1998, cited in IDS filed 3/27/2006).

Claim 14 is dependent from claim 1. Teachings of Clark et al regarding claim 1 are described in this office action in section 8.

Regarding claim 14, Clark et al teaches that the apparatus comprises optical reading well (Fig. 1, # 20) and further teaches well comprises electrodes (pg. 8, lines 16-18). Clark et al are silent about the chamber coated with electrically conducting polymer. However, coating of the chamber with an electrically conducting polymer was known in the art at the time of the claimed invention was made as taught by Lee, who teaches a reaction vessel, i.e., a chamber (Fig. 1, # 1) coated with an electrically conducting polymer (Fig. 1, # 3, pg. 11, lines 1-5). Lee also teaches that electrically conducting polymer coated reaction vessels provides an efficient system for rapid heating and cooling of reactions and temperature of the individual vessels is controlled

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independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the chamber of Clark et al with chamber coated with an electrically conducting polymer of Lee with a reasonable expectation of success.

An artisan would have been motivated to modify the chamber of Clark et al with the expected benefit of having electrically conducting polymer coated reaction vessels providing an efficient system for rapid heating and cooling of reactions and having temperature of the individual vessels controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

***Response to remarks from the Applicants***

***Claim rejections under 35 U.S.C. § 102(b)***

13. Applicant's arguments filed on November 4, 2008, with respect to claims 1, 3-5, 11, 15 and 17 as being anticipated by Leighton et al have been fully considered (Remarks, pgs. 9-10), but are moot in view of withdrawn rejection and new grounds of rejection as set forth in this office action necessitated by claim amendments.

***Claim rejections under 35 U.S.C. § 103(a)***

14. Applicant's arguments filed on November 4, 2008, with respect to claims 1, 2 and 5-16 as being unpatentable over combination of references have been fully considered (Remarks, pg. 10), but are moot in view of withdrawn rejections and new grounds of rejection as set forth in this office action necessitated by claim amendments.

***Conclusion***

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634